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ABSTRACT

The National Advisory Committee on Hyperkinesis and Food Additives paper summarized some research findings on the issue of the relationship between food-additive-free diets and hyperkinesis in children. Based on several challenge studies, it is concluded that the evidence generally refutes Dr. B. F. Feingold's claim that artificial colorings in the diet substantially aggravate the behavior of children with learning disabilities and hyperkinesis; yet these studies do not make it certain that such additives are utterly devoid of adverse effects in all children of all ages. (DLS)

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TO: The Nutrition Foundation

FROM: The National Advisory Committee on Hyperkinesis and Food Additives

SUBJECT: Statement Summarizing Research Findings on the Issue of the Relationship Between Food-Additive-Free Diets and Hyperkinesis in Children

For about 3 years, much publicity has been generated around the claim made by a California Pediatric Allergist, Dr. Ben Feingold, that at least 40% of the children with hyperactivity and learning disabilities show marked improvement when artificial food colors and flavors and naturally occurring salicylates are removed from their daily diet. It has been inferred from Dr. Feingold's claim that these agents, by some unknown mechanism, presumably allergenic, cause these behavioral disturbances. Because of the theoretical and practical implications of Dr. Feingold's statements, the Nutrition Foundation convened an advisory committee on hyperkinesis and food additives to examine the evidence and to assess the validity of these claims. This committee published a report in June 1975, pointing out that open clinical studies such as those conducted by Feingold were valuable for generating hypotheses but were not adequate to test them. It recommended the specific research strategies that are needed to adequately test Dr. Feingold's hypothesis. A few months later, the

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Federal Food and Drug Administration (FDA) also appointed a study committee that published a report recommending similar research strategies.

The strategies suggested by the Nutrition Foundation Advisory Committee and the FDA Committee were of two types. The first, designed to independently replicate Dr. Feingold's work involved placing hyperkinetic children on an additive-free diet and then determining how many children improved and the degree of their improvement. For this type of clinical experiment a well-defined population of hyperkinetic children and cooperating families would need to be recruited. Baseline ratings of their behavior while on a regular diet would be obtained by their mothers and fathers in the home situation and by teachers and trained observers at school. Similar observations using the same rating scales would then be made during the period on the additive-free diet and again when they were returned to their ordinary diet. Such experiments conducted by experienced researchers who are open-minded could determine the number of children who improved and the degree to which they improved.

Recognizing that such clinical experiments would be difficult to monitor due to problems in subject compliance and the difficulty of keeping the subjects and their families ignorant concerning the presence of additives in the diet, a second strategy was suggested. This strategy was designed to minimize the possibility of placebo effects on the children's observed behavior. Children who appeared to respond to the additive-free diet in open clinical trials would be challenged with foods especially prepared to contain specified

quantities of known food additives masked in such a fashion that neither the parents nor the children would know whether the challenge foods were additive-free placebo or contained the presumed offending agents. Since Dr. Feingold had the only known population of identified responders to the additive-free diet, it was strongly suggested that he participate in the challenge experiments as soon as a suitably masked material could be prepared. He agreed to do so.

Since the publication of the Advisory Committee Report, the challenge materials have been prepared by a food science committee from the food industry. A chocolate, which is permissible on the Feingold additive-free diet, effectively masks synthetic food colors and it has been possible to prepare chocolate bars and cookies in which the additive-free and additive-containing samples look and taste alike. Into these additive-containing desserts were incorporated the most common food colors--one bar containing half the amount of color additives ingested in the average American daily diet. Two of the additive-containing desserts, therefore, would offer the average amount of food colors estimated to be ingested daily.

In the past eighteen months, three different groups of scientists have conducted carefully controlled research projects employing the study designs recommended in the reports of the Advisory Committee to The Nutrition Foundation and the Study Committee of the FDA. Initial findings stemming from these studies were reported at the Nutrition Foundation annual meeting in Palm Springs, California in January 1977. This summary prepared by the Chairman of that session and of the National Advisory Committee on Hyperkinesis and Food Additives, reviews the human findings reported at the Nutrition Foundation meeting and

develops conclusions based upon these studies.

One study was conducted by Drs. C. Keith Connors and Charles H. Goyette at the University of Pittsburgh. Initially they found that a group of hyperkinetic elementary school children placed on an additive-free diet which contained natural salicylates showed at least 25% improvement in their behavior patterns. This was an open clinical trial and 28 out of 45 children showed this positive response. While remaining on the special diet with no medication, 16 children were then given the special food bars, blindly, according to the following schedule: half of the children were given the dessert that contained food colors for a set period of time and then for an equal period they were given the bars free from additives. The other half were on the opposite schedule. Behavior ratings were recorded and evaluated by the parents and teachers during the regular school days.

Sixteen of the 28 responding hyperkinetic children completed the blind challenge experiment. These children had demonstrated a 60% mean reduction in behavior problems as rated by the parents and a 35% reduction as rated by teachers when placed on the elimination diet in the open clinical trial. In the challenge experiments, no differences could be noted between the children receiving the placebo bars and those who received the food additives. Symptomatic levels generally remained low throughout the eight-week experimental phase in both groups. In other words, children whose behavior improved during the open clinical trial on the additive-free diet did not deteriorate as measured by global parent and teacher ratings when they received the challenge materials. However, an interesting new observation was made on the children who were examined using special tests

for attention and distractability one to two hours after ingestion of the challenge materials. Transient decrements in attention lasting a few hours were noted with the additive-containing substances but not with the placebo. Connors now suggests that the action of the putative offending substances may be pharmacological and of very brief duration. Their effects, therefore, would not be noted when global symptomatic rating scales over extended observation periods are used. He stresses the need for additional research, especially on his newer observations.

A second study was conducted at the Department of Neurology of the University of Wisconsin Medical School by Harley and co-workers. In the first part of their study, they used two diets prepared by a nutritionist and administered under strict double blind conditions. One diet contained additives, the other was selected to be additive-free. Multiple measurements were made by parents, teachers and psychologists. Unlike Connors findings and those from other open studies, they found very few children for whom the diet was at all helpful. The reasons for the different results in these studies are not entirely clear. The Wisconsin group possibly used a different and less sick population. They were also particularly careful to keep the family in ignorance as to when the additive-free diet was being used. This may account for the difference in results. In the Connors study and in the other open studies, the parents and the child always knew when the special additive-free diet began, and the outcome may have been affected by the family's expectations and their strong desire to have this form of treatment work. This phenomenon is well known in behavioral research and is called a "placebo effect." Following their initial study, the Wisconsin group selected nine children who seemed

to show at least minimal improvement on the special diet and challenged them with the food bars in a double blind study. No difference in behavior between additive-free and additive-containing food bars was detected, except in one child. The group concluded that Dr. Feingold's hypothesis was, in general, incorrect, but that there might be an occasional young child who genuinely reacts adversely to food colorings in the manner predicted by Dr. Feingold.

A third study was conducted by Dr. J. Ivan Williams and his group at the University of Western Ontario, in conjunction with Dr. Douglas N. Cram at the Middlesex, London District Health Unit in Ontario, Canada. They studied not only the effects of the additive-free diet, but they also compared the effectiveness of this diet with stimulant medications commonly used for treatment. A crossover design was used so that each of the 26 children was in each treatment condition, thereby serving as his or her own control. Both the diet and the stimulants were administered under double blind conditions.

Behavior checklist ratings were used as outcome measures, and for both parents and teachers, the ratings indicated strong improvement in behavior when the child was taking medication.

There were some diet effects noted in parent ratings. When the children were on medication, the parent ratings were worse when the children were eating cookies with artificial food coloring than when they were eating cookies without artificial food coloring.

The teacher ratings showed strong diet effects. Contrasted with parent ratings, the diet effects for teachers were most marked when the children were on placebo medication. The children ate cookies in the morning and in the afternoon, and the ratings were worse when they were eating the cookies with artificial food coloring than when eating cookies free of artificial food coloring. While there are some inconsistencies in the findings, the results based on the teacher ratings suggest the need for further studies for verification.

The evidence available so far generally refutes Dr. Feingold's claim that artificial food colorings in the diet substantially aggravate the behavior of children with learning disability and hyperkinesis. (Therefore, initiation of major changes in food manufacture or labeling by legislation appears unnecessary and certainly premature.) On the other hand, one cannot yet be certain that food additives are utterly devoid of adverse effects in all children of all ages. A larger and more diverse number of children are needed for study than those thus far tested on the elimination diet or in the challenge experiment. It is especially regretful that Dr. Feingold, who has claimed the successful treatment of hundreds of children in open clinical trials with the additive-free diet, has yet to report the results of blind challenge tests. Several new groups of investigators have become involved in this research and their results should help in reaching definitive conclusions. Studies currently under-

way have yielded some findings that must be pursued with further research. For example, there is a hint from the Wisconsin studies that young preschool children may be more sensitive to food additives than older children. The preliminary results from Pittsburgh, which seems to show transient detrimental effects on attention span shortly after ingestion of the challenge additives, also deserve further study. These results may resemble the observation of Williams that children not receiving stimulants were noted by their teachers to exhibit somewhat worse behavior after ingestion of challenge additives. Should these observations be sustained, it would be suggested that some additives might have a pharmacological action, quite different from that suggested by Feingold, but nonetheless potentially detrimental.

It is apparent that what seems on the surface to be a simple research problem, namely the rigorous testing of the Feingold hypothesis to yield a clean yes or no answer, has turned out to be more subtle and complex. Many factors have contributed to this. Behavioral change is the deciding factor in all of this research, and behavior and its measurement is so dependent upon psychological influences in the home and school that it is difficult to isolate the single variable of food additives. In addition, the problem of biological variance of unknown dimensions makes it difficult to be certain that some population may not be susceptible to additives. Finally, only a small number of investigators are involved in this type of research. Each of these has exerted his right to scientific freedom by conducting

research which, while staying within the limits of the basic strategies suggested by the FDA and the Nutrition Foundation Advisory Committee, nonetheless expresses his unique interests and motivations. In the long run, these variations will help to give better answers, but at this moment it makes comparison of the work of different groups difficult to interpret.

Despite the limitations of the present evidence it should be emphasized that there are presently no data to suggest that initiation of major changes in food manufacture or labeling is urgently needed.

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